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183

03/16/90

☐ This application has been examined ☒ Responsive to communication filed on Nov. 13, 1989 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ——— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-45 are pending in the application.
   Of the above, claims 2-4, 6-18, 20-21, 23, 29-31, 34-40 and 43-45 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 183.

Applicant's election with traverse of Group I, claims 1, 5, 19, 22 and 32-33 and the ultimate species amylin amide in Paper No. 8 is acknowledged. The traversal is on the grounds(s) that the inventions in Group I and III are not distinct since the burden is on the PTO to provide an example of the productin being useful in a different process, that Groups I and II do not meet the criteria for combination/subcombination restriction since insulin is old in the art and not patentable that Groups I and IV is not of mutually exclusive species in intermediate final product, Group IV is to a process of monitoring the effects of administration of Group I products and not the use of Group I products, the invention in Group I and VII or only part product and process of making. This is not found persuasive because the inventions as grouped in paper No. 6 are patentable distinct for the reasons stated therein.

The term "hypotension" in paper No. 6 was intended to read hypertension.

Groups I and II are proper subcombiantion/combination since a method of treatment with amylin along or insulin along is not dependent upon

the combination nor is as applicant has admitted is the combination dependent upon insulin.

Inventions of Group I and IV are distinct since the method of monitoring the amylin is not related to the amylin per se or method of preparing amylin.

Groups I and VII meet the criteria for product and process of making and therefore, the restriction between them is proper.

The requirement is still deemed to be proper and is therefore made FINAL.

Claims 2-4, 6-18, 20-21, 23, 29-31 and 34-40 and 43-45 stand withdrawn from further consideration as being for a nonelected invention, 37 CFR 1.142(b).

The Examiner appreciates Applicants pointing out that claim 9 appears in both Group I and Group III. the claim was inadvertantly included in Group I.

Claims 24-28 and 41-42 are included (to the extend they ~~record~~ read on the elected invention) with the elected invention since they are linking claims. The office action listed 41-41 by error and it should have read 41-42.

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Amylin is a product of nature and therefore is unpatentable without some alteration (increased purity, biological activity, etc). See M.P.E.P. 706.03(a).

Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 are rejected under 35 U.S.C. 101 because the invention as disclosed is inoperative and therefore lacks patentable utility.

Applicant has alleged that the utility of amylin is in the treatment of Diabetes mellitus or hyopglycaemia. However, the disclosure contains no factual data (experimental or clinical or effective dosage) that supports the alleged utility. Since the product is intended for in vivo administration, Applicant must have in vivo data to support the utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant has not enable one skilled in the art how to use the invention effectively for treating diabetes mellitus or hypoglcaemia. See above paragraph or lack of utility for further explanation of rejection.

Applicant's disclosure is not enabling as to the preparation and identification of the active subfragment(s), conservative variants or function peptides or amylin or to the effective use of those products as well as CGRP peptides for treating diabetes mellitus or hypoglycaemia.

Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one (1) year prior to the date of application for patent in the United States.

Claims 1, 22 and 41-42 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over either the Cooper et al article "Purification and Characterization of Peptide from Amyloid-Rich Pancreases of Type 2 Diabetic Patients, the Westermark et al. article or the Clark et al. article.

Each of these articles teach amylin or peptides which are probably identical to amylin. See applicant's disclosure on pages 2-3.

These products are inherently ~~by~~ the same as those of applicants' claims. Copies of the references are not enclosed since applicant already has copies.

Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected for the following reasons:
(a) The terms "functional fragment", conservative variant and "subfragment" are indefinite as to the scope of peptides includes in the claims.,
(b) Claim 5 is totally indefinite since it claims a method of preparing a product, but recites forming a solution for parenteral administrating,
(c) claim 19 is indefinite as to the scope of the term "active subfragments.
(d) Claim 22 and 24-28 and 41-42 is functional at the point of novelty since it does not define all the components or the amounts of them in the preparation which are responsible for the delayed release of the peptide,
(e) claims 32-33 and 41-42 fail to particularly point out and distinctly claim the amounts of each component in the suspenion. Also, applicant should add the term "composition" after suspension for proper claim terminology.

Claims 24-28 and 41-42 objected to under 37 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP 608.01(i). ~~Accordingly, ---------- not been further treated on the merits.~~

Any inquiry concerning this communication should be directed to Lester L. Lee at telephone number 703-557-0664.

Lee:ew
03-01-90

Lester L. Lee
LESTER L. LEE
PRIMARY PATENT EXAMINER
ART UNIT 183
3